

## REMARKS

This Response to Office Action is respectfully submitted in response to the Office Action mailed March 20, 2008, in which a shortened statutory period for response of three (3) months was set. It is timely in view of the Petition for Extension of Time filed concurrently herewith. A Notice of Appeal is being filed respectfully concurrently herewith. Applicants request reconsideration in light of the following remarks.

The Office Action of March 20, 2008 again rejected claims 75-84 under 35 U.S.C. 102(b) as being anticipated by JP Patent Application No. Hei-8-143442 to Matsuura et al (JP '442). Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action bases the foregoing rejection on the statement that JP '442 teaches "a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added.... The ground matter is heated but to a temperature which could read on 5°C." [Office Action, p. 3] In response to applicants' earlier submission asserting that such a treatment process would not result in soy extract having trypsin inhibitory activity, the Office Action asserts that the applicants have not provided evidence of facts set forth in their earlier submission and that "STI would still be in the extract thus reading on the claims, since the STI was not diffused as applicant has argued." [Office Action, p. 4]

Applicants respectfully submit that JP '442 does not anticipate the limitations of independent claim 75 as alleged in the Office Action and respectfully request reconsideration of the foregoing rejection in view of the ensuing discussion and attached Declaration of Miri Seiberg ("Seiberg Declaration") respectfully submitted concurrently herewith.

Applicants respectfully point out that the soybean extract of JP '442 would *not* contain STI. As set forth in the accompanying Seiberg Declaration, the mere process of permitting soybeans to soak in water will not enable STI to diffuse into the soaking liquid. This conclusion is based upon the knowledge of those skilled in the art that, for biological molecules, the coefficients of diffusion normally range from  $10^{-11}$  to  $10^{-10}$  m<sup>2</sup>/s. The diffusion coefficient of STI is much lower, so it is not measured "per second" but "per day" at 24°C. As it is a biological molecule, in accordance with the Seiberg Declaration, the diffusion coefficient of STI is thus so low that it is highly unlikely that any significant amount of STI would diffuse from soybeans into soaking liquid in which it resides [Seiberg Declaration, ¶¶6, 7].

The Office Action argues that should applicants be correct in the assertion that STI would not diffuse into water in which soybeans were being soaked, "...the STI would still be in

the extract thus reading on the claims, since the STI was not diffused as applicant has argued.”  
[Office Action, p. 4]

Applicants respectfully submit that, in accordance with JP ‘442, if the STI remained in the soybeans, it would not be present in the compositions that JP ‘442 describes. This is because the compositions described therein contain “*extract liquid of soybeans*” [JP ‘442 Translation, p. 2, Claim 1] (emphasis added), rather than the soybeans (even the crushed soybeans) themselves. JP ‘442 states:

The present inventors focused attention on a *soaked liquid of soybeans*, which is generated as a by-product during the production of tofu, and conducted studies for aiming at making *efficient use of the soaked liquid*...[JP ‘442 Translation, p. 4, l. 16-19] (emphasis added)

JP ‘442, moreover, indicates that the process involves soaking the soybeans at varying temperatures for varying times and then, “[a]fter the soaking, separation into soybeans and soaked liquid is carried out, and *this soaked liquid is used as a raw material*.” [JP ‘442, p. 7, l. 2-4] (emphasis added). It is not the soybeans, but the *liquid in which they have soaked*, which is the extract utilized in the compositions of JP ‘442. Therefore, if the STI does not diffuse out of the soybeans, it remains in the soybeans and will not appear in the extract of the described compositions.

Furthermore, JP ‘442 indicates that even in the instance in which there is a “protein fraction” generated by a process, this protein fraction is precipitated out of the extract that is to be used in topical compositions, as follows:

...In the case where whey generated as a by-product during the production of a soy protein isolate is used as a raw material, for example, 10 times volume of water is added to defatted soybeans, the pH thereof is adjusted to 7.5 with sodium hydroxide, and the mixture is stirred at room temperature for 2 hours. Then, insoluble matter (bean curd refuse) is removed by solid-liquid separation, whereby *a protein-containing liquid is obtained*. *The pH of this liquid is adjusted to 4.5 with hydrochloric acid to allow the proteins to precipitate, and solid-liquid separation into a protein fraction (soy protein isolate) and whey is carried out*. Then, the soluble sugar content in the whey is adjusted and *the whey is mixed with a hydrophilic ointment base*, whereby an external preparation for skin is prepared...[JP ‘442, p. 8, l. 11-24] (emphasis added)

Thus, in response to the assertion set forth in the Office Action that STI would be present in the extract of the process described in JP ‘442, it can be seen, that the soybean extract to which JP ‘442 refers is *not* a protein-containing fraction.

Accordingly, applicants respectfully submit that JP '442 does not disclose, teach or suggest explicitly or inherently the subject matter of claims 75-84. Applicants therefore respectfully request reconsideration of the rejection of claims 75-84 under 35 U.S.C. 102(b) as being anticipated by JP 408143442.

The Office Action of March 20, 2008 again rejected claims 75-84 under 35 U.S.C. 102(a) as being anticipated by JP Patent No. 410226642 (abstract). Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action states that JP '642 teaches "an extract of soybeans used to treat psoriasis. The extract can be applied in an ointment form." [Office Action, p. 4] Applicants respectfully request reconsideration of the foregoing rejection in view of the ensuing discussion.

In response to applicants' earlier submission asserting that the ointment of JP '642 would not contain trypsin inhibitory activity, the Office Action states that the applicants have not provided evidence of facts set forth in their earlier submission and that "[US Patent 5141746] only shows one particular method of extracting genistein and this still does not prove applicant's allegation. Further, JP '642 refers to 'pure genistein' in the context that the soybean product which can have a low concentration is usable in place of pure genistein." [Office Action, p. 4]

Applicants respectfully submit that JP '642 does not anticipate the limitations of independent claim 75 as alleged in the Office Action. Applicants respectfully point out that the genistein extracted from the soybeans would not contain STI even at "low concentrations". As set forth in the accompanying Seiberg Declaration, genistein extracted from soybeans at low concentrations (used by JP '642) will not contain STI activity because genistein, an isoflavone, is extracted from soybeans using organic solvents (Seiberg Declaration, ¶4). STI is denatured by organic solvents [Seiberg Declaration ¶3]. Proteins, including STI, separate out of the organic phase in organic extraction processes while genistein and other isoflavones remain in the organic phase. [Seiberg Declaration, ¶4]. Thus, STI would separate from genistein during the organic extraction process; even if trace amounts of STI appeared in the organic phase, such protein molecules would be denatured and, therefore, inactive [Seiberg Declaration, ¶5].

In view of the foregoing discussion, applicants respectfully submit that JP '642 neither inherently nor explicitly suggests or describes the compositions or methods of applicants' invention. Applicants therefore respectfully request reconsideration of the foregoing rejection in view of JP '642.

For the foregoing reasons, applicants respectfully submit that the above-captioned application is now clearly in condition for allowance. Accordingly, favorable reconsideration of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750.

Respectfully submitted,

/Andrea L. Colby/

---

Andrea L. Colby  
Reg. No. 30,194  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2792  
August 15, 2008